A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after Final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on October 21, 2010 has been entered.

Claims 3 and 10-13 are canceled. Claims 1, 2 and 4-9 are pending. Methods of treating irritable bowel syndrome, the elected invention, remains under consideration.

Newly amended claim 9 is now directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Claim 9 was drawn to a method of treating irritable bowel syndrome comprising administering balsalazide together with mesalazine for the treatment of diarrhea-predominant irritable bowel syndrome. Following an amendment to claim 9 on October 21, 2010, the claim is presently drawn to the treatment of diverticulitis comprising administering rifaximin and balsalazide. Further search and consideration are required.

Since Applicants have received Actions on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 9 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

The rejection set forth under 35 U.S.C. 103 in the last Office Action is withdrawn.

The disclosure is objected to for the following informality:

The capitalization of irritable bowel syndrome in claims 2, 3 and 9 is unnecessary.

Appropriate correction is required.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2 and 4-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin et al., U.S. Patent 6,861,053.

Lin teaches the administration of both balsalazide, a 5-aminosalicylic acid, and the antibiotic rifaximin, in the treatment of irritable bowel syndrome. See column 16, line 60, to column 17, line 2, and column 17, lines 9-27. At least partially eradicating the small intestine bacterial overgrowth is the therapeutic goal. Lin suggests this bacterial overgrowth is a causal factor in the pathogenesis of irritable bowel syndrome. The administration of rifaximin is an especially preferred embodiment. See claim 5, column 29. As required by instant claims 6 and 7, additional 4- and 5-aminosalicylates are disclosed in column 17, lines 13-27, such as ipsalazide, sulfasalazine, olsalazine and mesalazine. The open language of the present claims allows for the administration of any number of additional active or inactive agents. Following administration,

balsalazide is delivered intact to the colon where it is cleaved by bacterial azoreduction to release equimolar quantities of mesalamine, the therapeutically active portion of the molecule, and 4-aminobenzoyl-β-alanine, an only minimally absorbed and largely inert portion of the molecule.

Thus, in view of Lin's teaching, one skilled in the gastroenterology art would have been motivated to administer the prodrug balsalazide and the antibiotic rifaximin with a reasonable expectation of treating IBS in a human through the mechanism of eradicating small intestinal bacterial overgrowth. See *In re Diamond and Kellman*, 149 USPQ 562 (CCPA 1966), which supports the obviousness of combining two drugs that are known to be useful for the same purpose.

No claim is allowed.

Applicants' Amendment necessitated the new ground of rejection presented in this Office Action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached on 10:30 AM-7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Jeff Lundgren, may be reached on 591-272-5541. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

February 8, 2012

/Phyllis G. Spivack/
Primary Examiner, Art Unit 1629